## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

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In Re: PHARMACEUTICAL INDUSTRY

AVERAGE WHOLESALE PRICE

LITIGATION

Master File No. 01-CV-12257-PBS

MDL NO. 1456

THIS DOCUMENT RELATES

TO ALL ACTIONS

Judge Patti B. Saris

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# DEY INC.'S ANSWER TO PLAINTIFFS' CORRECTED AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT MODIFIED PER THE COURT'S INSTRUCTIONS AT THE NOVEMBER 21, 2003 HEARING WITH AMGEN AMENDMENTS

Defendant Dey, Inc. ("Dey"), by its attorneys, Kelley Drye & Warren LLP, for its Answer to Plaintiffs' Corrected Amended Master Consolidated Class Action Complaint Modified Per the Court's Instructions at the November 21, 2003 Hearing With Amgen Amendments (the "AMCC"), states:

#### I. INTRODUCTION

- 1. Dey admits that Plaintiffs purport to bring this action as alleged in Paragraph 1 of the AMCC, but otherwise denies the allegations in Paragraph 1 of the AMCC.
- 2. To the extent the allegations in Paragraph 2 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations, but otherwise denies the allegations in Paragraph 2 of the AMCC.

- 3. Dey denies the allegations in Paragraph 3 of the AMCC, except admits that it reports certain pricing information for its medicines to pharmaceutical industry pricing publications.
  - 4. Dey denies the allegations in Paragraph 4 of the AMCC.
  - 5. Dey denies the allegations in Paragraph 5 of the AMCC.
  - 6. Dey denies the allegations in Paragraph 6 of the AMCC.
  - 7. Dey denies the allegations in Paragraph 7 of the AMCC.
  - 8. Dey denies the allegations in Paragraph 8 of the AMCC.
- 9-10. To the extent the allegations in Paragraphs 9 and 10 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations, but otherwise denies the allegations in Paragraphs 9 and 10 of the AMCC.
- 11. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11 of the AMCC, except denies that Plaintiffs are entitled to any relief on account of the medicines attributed to Dey in Exhibit A to the AMCC.
- 12. The Court dismissed Count I in its Order dated February 25, 2004. To the extent a response is required, Dey denies the allegations in Paragraph 12 and Count I of the AMCC.
- 13-21. Dey denies the allegations in Paragraphs 13 through 21 of the AMCC, except admits that Plaintiffs purport to bring this action as a class action, and that Plaintiffs seek relief as against Dey under Counts II, III, IV, and IX, as alleged in Paragraphs 13-15, and 20 of the AMCC. To the extent the allegations in paragraphs 13-21 of the AMCC are directed to persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations.

#### II. JURISDICTION AND VENUE

- 22. Dey denies the allegations in Paragraph 22 of the AMCC, except Dey avers that it is not a defendant in the action brought by Plaintiff Board of Trustees of Carpenters and Millwrights of Houston and Vicinity Welfare Trust Fund, referenced in Paragraph 22 of the AMCC, and, therefore, denies having knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations concerning this action.
- 23-25. Dey denies the allegations in Paragraphs 23 through 25 of the AMCC, and refers the Court to the Order dated April 30, 2002 as the best evidence of its contents.

#### III. PARTIES

- 26-31. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 26 through 31 of the AMCC and, therefore, denies those allegations.
- 32-36. Dey denies the allegations on Paragraphs 32 through 36 of the AMCC, except denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 32 through 36 of the AMCC to the extent those allegations concern the knowledge, conduct or actions of persons, entities or defendants other than Dey.
- 36(a). Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 36(a) of the AMCC and, therefore, denies those allegations.
- 37-38. To the extent the allegations in Paragraphs 37 and 38 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 37 and 38 of the AMCC.

- 39-78. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 39 through 78 of the AMCC insofar as they are directed to other defendants. To the extent the allegations in Paragraphs 39 through 78 of the AMCC are deemed to include allegations against Dey, they are denied.
- 79. Dey admits that it is a Delaware corporation with its principal place of business located at 2751 Napa Valley Corporate Drive, Napa, California and that Merck KGaA is a corporation organized and existing pursuant to the laws of the Federal Republic of Germany and is the ultimate parent of Dey. Dey denies the remaining allegations in Paragraph 79 of the AMCC.
- 80. Dey admits that it is a specialty pharmaceutical company that develops, manufactures, and markets certain generic drugs used in the treatment of, among other things, respiratory diseases and allergies. Dey also admits that it had net sales in 1998 of \$266 million. Dey denies the remaining allegations in Paragraph 80 of the AMCC.
  - 81. Dey admits the allegations of paragraph 81 of the AMCC.
  - 82. Dey admits the allegations of paragraph 82 of the AMCC.
- 83. Dey admits that it is a specialty pharmaceutical company that manufactures, among other pharmaceuticals, ipratropium bromide, metaproterenol sulfate, and Accuneb. Dey denies the remaining allegations in Paragraph 83 of the AMCC.
- 84-131. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraphs 84 through 131 of the AMCC insofar as they are directed to other defendants. To the extent the allegations in Paragraphs 84 through 131 of the AMCC are deemed to include allegations against Dey, they are denied.

#### IV. GENERAL ALLEGATIONS APPLICABLE TO ALL DEFENDANTS

- 132. Dey denies the allegations in Paragraph 132 of the AMCC.
- 133. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 133 of the AMCC, except admits patients receive drugs from physicians, pharmacies, and other health care providers.
- 134. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 134 of the AMCC, except denies that it was "aware" of the actions and knowledge of the Medicare Program and unspecified "end payors."
- 135. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 135 of the AMCC, except Dey admits that pharmaceutical industry pricing publications periodically report AWPs for prescription medicines sold in the United States.
- 136. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 136 of the AMCC, and refers the Court to the 1999 edition of the *Red Book* and the June 1996 Dow Jones News article cited in Paragraph 136 of the AMCC as the best evidence of their contents.
  - 137. Dey denies the allegations in Paragraph 137 of the AMCC.
  - 138. Dey denies the allegations in Paragraph 138 of the AMCC.
  - 139. Dey denies the allegations in Paragraph 139 of the AMCC.
  - 140. Dev denies the allegations in Paragraph 140 of the AMCC.
  - 141. Dey denies the allegations in Paragraph 141 of the AMCC.
  - 142-144. Dey admits the allegations in Paragraphs 142 through 144 of the AMCC.

- 145. Dey denies the allegations in Paragraph 145 of the AMCC, and refers the Court to 42 C.F.R. § 405.517 as the best evidence of its contents.
  - 146. Dey denies the allegations in Paragraph 146 of the AMCC.
- 147. Dey denies the allegations in Paragraph 147 of the AMCC, and refers the Court to 42 C.F.R. § 405.517 as the best evidence of its contents.
- 148. Dey denies the allegations in Paragraph 148 of the AMCC, and refers the Court to the Program Memo AB-99-63 cited in Paragraph 148 of the AMCC as the best evidence of its contents.
- 149. Dey denies the allegations in Paragraph 149 of the AMCC, and refers the Court to the Program Memo AB-99-63 cited in Paragraph 149 of the AMCC as the best evidence of its contents.
  - 150-151. Dey admits the allegations in Paragraphs 150 through 151 of the AMCC.
- 152. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 152 of the AMCC, except admits that there are no government regulations describing how AWPs are calculated, nor any other statutory or regulatory definitions or descriptions of AWPs, and that it reports certain pricing information for its medicines to pharmaceutical industry pricing publications.
- 153-154. Dey denies the allegations in Paragraphs 153 and 154 of the AMCC, and refers the Court to the April 2003 OIG report cited in Paragraphs 153 and 154 of the AMCC as the best evidence of its contents.
- 155. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 155 of the AMCC, except admits it is aware that certain investigations are occurring.

- 156-157. Dey denies the allegations in Paragraphs 156 and 157 of the AMCC, and refers the Court to the September 28, 2000, letter from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America cited in Paragraphs 156 and 157 of the AMCC as the best evidence of its contents.
- 158-159. To the extent the allegations in Paragraphs 158 through 159 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations. Dey denies the remaining allegations in Paragraphs 158 through 159 of the AMCC, except admits it is aware that certain investigations are ongoing.
- 160. To the extent the allegations in Paragraph 160 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations, except admits that it provided AWPs to the pharmaceutical compendia.
- 161-184. To the extent the allegations in Paragraphs 161 through 184 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations, and denies the remaining allegations in Paragraphs 161 through 184 of the AMCC.
  - 185. Dey denies the allegations in Paragraph 185 of the AMCC.
  - 186. Dey denies the allegations in Paragraph 186 of the AMCC.
- 187. To the extent the allegations in Paragraph 187 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 187.

- 188. Dey denies the allegations in Paragraph 188 of the AMCC.
- 189. Dey denies the allegations in Paragraph 189 of the AMCC, and refers the Court to the complaint cited in Paragraph 189 as the best evidence of its contents.
  - 190. Dey denies the allegations in Paragraph 190 of the AMCC.
- 191. To the extent the allegations in Paragraph 191 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 191.
- 192. To the extent the allegations in Paragraph 192 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations, and refers the Court to the 2003 CMS document cited in Paragraph 192 of the AMCC as the best evidence of its contents. Dey denies that Plaintiffs have accurately characterized any alleged CMS finding, opinion, statement or conclusion. Dey admits that it sells its medicines in a competitive market and, as such, takes steps to keep certain information relating to its medicines confidential. Dey denies the remaining allegations in Paragraph 192 of the AMCC.
- 193-196. To the extent the allegations in Paragraphs 193 through 196 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 193 through 196 of the AMCC.
  - 197-199. Dey denies the allegations in Paragraphs 197 through 199 of the AMCC.

## V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT

- 200. To the extent the allegations in Paragraph 200 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 200 of the AMCC.
- 201-348. The allegations in Paragraphs 201 through 348 of the AMCC are directed to another defendant and require no response from Dey. To the extent allegations in Paragraphs 201 through 348 of the AMCC are deemed to require a response, they are denied.
  - 349. Dey denies the allegations in Paragraph 349 of the AMCC.
- 350. Dey denies the allegations in Paragraph 350 of the AMCC, except admits that the governmental agencies listed in Paragraph 350 of the AMCC have conducted investigations concerning pricing in the pharmaceutical industry and that Dey, among others, has participated in certain of such investigations.
- 351. Dey denies the allegations in Paragraph 351 of the AMCC, and refers the Court to the editions of the *Red Book* and the September 25, 2000, letter from Representative Bliley to Nancy-Ann DeParle as the best evidence of their contents.
- 352-353. Dey denies the allegations in Paragraphs 352 and 353 of the AMCC, except admits that the Attorneys General of Texas, West Virginia and Connecticut have commenced actions against Dey, and refers the Court to the pleadings in those actions as the best evidence of their contents.
- 354. Dey denies the allegations in Paragraph 354 of the AMCC, except admits that it reported certain pricing information for its medicines to pharmaceutical industry pricing publications during the purported Class Period and that it reported suggested AWP prices, and

further admits that it prepared the document cited in Paragraph 354(a) of the AMCC (DL-CA 00120), but Dey states that this document is the best evidence of its contents and denies that the conclusions Plaintiffs draw from this document are accurate. Dey denies that it prepared the document cited in Paragraph 354(b) of the AMCC (DL-CA 00080), except Dey admits that the referenced, handwritten notations on DL-CA 00080 were made by a Dey employee.

355. Dey denies the allegations in Paragraph 355 of the AMCC, except admits that it prepared the documents cited in Paragraph 355(a) and 355(b) of the AMCC (DL-TX-0014029 and DL-TX-0014439), but Dey states that these documents are the best evidence of their contents and denies that the conclusions Plaintiffs draw from these documents are accurate.

356-358. To the extent the allegations in Paragraphs 356 through 358 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey states that the reports published by the OIG (OEI-03-01-00410, March 2002), cited and referred to in Paragraphs 356 and 357 of AMCC, and the report published by the GAO (*see* "MEDICARE: Payments for Covered Outpatient Drugs Exceed Providers' Cost"), cited in Paragraph 358 of the AMCC, are the best evidence of their contents, but Dey denies that Plaintiffs have accurately characterized any alleged finding, opinion, statement or conclusion contained in these documents. Dey admits that albuterol sulfate is a multiple-source drug manufactured and/or marketed by Dey. Dey denies the remaining allegations in Paragraphs 356 through 358 of the AMCC.

359. To the extent the allegations in Paragraph 359 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations

and, therefore, denies those allegations. Dey states that the report published by the DHHS cited in Paragraph 359 of AMCC is the best evidence of its contents, but Dey denies that Plaintiffs have accurately characterized any alleged finding, opinion, statement or conclusion contained in such report. Dey admits that it sells its medicines at prices below AWP, which is a non-discounted list price. Dey denies the remaining allegations in Paragraph 359.

360. To the extent the allegations in Paragraph 360 of the AMCC refer to the knowledge, conduct or actions of persons or entities other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies that the document cited as the source for "Table 1" in paragraph 360 of the AMCC is a document prepared by Dey and further denies that this document reflects any conduct by or knowledge of Dey. Dey further denies that "Table 1" in paragraph 360 of the AMCC accurately reflects the contents of the cited document (DL-TX 0011179), and otherwise denies the allegations in Paragraph 360.

361-362. To the extent the allegations in Paragraphs 361 and 362 of the AMCC refer to the knowledge, conduct or actions of persons or entities other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey admits that it prepared the document cited in Paragraph 362 of the AMCC (DL-TX-0004775), but Dey states that this document is the best evidence of its contents and denies that the conclusions Plaintiffs draw from this document are accurate. Dey denies the remaining allegations in Paragraphs 361 and 362.

15-363. To the extent the allegations in the Paragraph erroneously denominated "15" and Paragraph 363 of the AMCC refer to the knowledge, conduct or actions of persons or entities other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the

truth of those allegations and, therefore, denies those allegations. Dey admits that it prepared the document cited in the Paragraph erroneously denominated "15" of the AMCC (DL-TX-0024844), but Dey states that this document is the best evidence of its contents and denies that the conclusions Plaintiffs draw from this document are accurate. Dey denies the remaining allegations in the paragraph erroneously denominated "15" and Paragraph 363 of the AMCC.

364-540. The allegations in Paragraphs 364 through 540 of the AMCC are directed to another defendant and require no response from Dey. To the extent allegations in Paragraphs 364 through 540 of the AMCC are deemed to require a response, they are denied.

## VI. PLAINTIFFS' CLAIM FOR DAMAGES

541. Dey denies that Plaintiffs have suffered damages or injuries as alleged in Paragraph 541 of the AMCC. Dey denies having knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 541 of the AMCC and, therefore, denies those allegations.

#### VII. PLAINTIFFS' CLAIMS CONCERNING TOGETHER RX

542-594. The allegations in Paragraphs 542 through 594 of the AMCC are directed to another defendant and concern claims which are not asserted against Dey. Therefore, these paragraphs of the AMCC require no response from Dey. To the extent a response is required, Dey denies all allegations contained in Paragraphs 542 through 594 of the AMCC.

#### VIII. CLASS ALLEGATIONS FOR THE PURPORTED "AWP PAYOR CLASS"

595-598. Dey admits that Plaintiffs purport to bring this action as alleged in Paragraphs 595 through 598 of the AMCC, but Dey denies that Plaintiffs are entitled to maintain this action in the manner alleged, and otherwise denies the allegations in Paragraph 598.

599-603. Dev denies the allegations in Paragraphs 599 through 603 of the AMCC.

# IX. CLASS ALLEGATIONS FOR THE PURPORTED "TOGETHER RX CLASS"

604-618. The allegations in Paragraphs 604 through 618 of the AMCC concern a purported class of plaintiffs which do not assert claims against Dey. Therefore, these paragraphs of the AMCC require no response from Dey. To the extent a response is required, Dey denies all allegations contained in Paragraphs 604 through 618 of the AMCC.

#### COUNT I (RICO)

619-646. The Court dismissed Count I in its Order dated February 25, 2004.

Accordingly, Dey does not respond to Paragraphs 619 through 646 of the AMCC. To the extent a response is required, Dey denies all allegations contained within Count I of the AMCC.

#### **COUNT II (RICO)**

- 647. Answering Paragraph 647 of the AMCC, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 646 of the AMCC.
- 648. Dey denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against Dey under Count II, and Dey denies the remaining allegations in Paragraph 648 of the AMCC.
  - 649. Dey denies the allegations in Paragraph 649 of the AMCC.
- 650. Dey denies having knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 650 and, therefore, denies those allegations.
- 651-655. To the extent the allegations in Paragraphs 651 through 655 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey states that the unidentified "industry report" cited in Paragraph 655 of the AMCC is the best evidence of its contents. Dey denies that

Plaintiffs have accurately characterized any alleged "industry report" finding, opinion, statement or conclusion. Dey denies the remaining allegations in Paragraphs 651 through 655 of the AMCC.

656-678. To the extent the allegations in Paragraphs 656 through 678 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 656 through 678 of the AMCC.

679. Dey denies the allegations in Paragraph 679 of the AMCC.

#### COUNT III (DECLARATORY RELIEF)

- 680. Answering Paragraph 680 of the AMCC, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 679 of the AMCC.
- 681. To the extent the allegations in Paragraph 681 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraph 681 of the AMCC.
- 682-683. Answering the first sentence of Paragraph 682 of the AMCC, Dey refers to and incorporates its response to Paragraph 681 of the AMCC. To the extent the allegations in Paragraphs 682 and 683 of the AMCC refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 682 and 683 of the AMCC.

#### **COUNT IV (CONSUMER PROTECTION STATUTES)**

- 684. Answering Paragraph 684 of the AMCC, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 683 of the AMCC.
- 685. Dey admits that Plaintiffs purport to bring this action and to seek relief under Count IV of the AMCC as alleged in Paragraph 685, but Dey denies that Plaintiffs are entitled maintain this action as alleged or to any relief against Dey under Count IV. Dey denies the remaining allegations in Paragraph 685 of the AMCC.
- knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey admits that its principal place of business is located in Napa, California. Dey admits that certain states have enacted consumer protection laws, but Dey denies that it has violated such laws or that Plaintiffs or any putative class members are entitled to relief under such laws. Dey denies the remaining allegations in Paragraph 686 of the AMCC.
- 687-691. To the extent the allegations in Paragraphs 687 through 691 of the AMCC and subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 687 through 691 of the AMCC.

#### **COUNT V (CLAYTON ACT – TOGETHER RX)**

692. Answering Paragraph 692 of the AMCC, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 691 of the AMCC.

693-698. The allegations in Paragraphs 692 through 698 of the AMCC are directed to another defendant and concern claims which are not asserted against Dey. Therefore, these paragraphs of the AMCC require no response from Dey. To the extent a response is required, Dey denies all allegations contained in Paragraphs 693 through 698 of the AMCC.

#### **COUNT VI (SHERMAN ACT – TOGETHER RX)**

699. Answering Paragraph 699 of the AMCC, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 698 of the AMCC.

700-704. The allegations in Paragraphs 700 through 704 of the AMCC are directed to another defendant and concern claims which are not asserted against Dey. Therefore, these paragraphs of the AMCC require no response from Dey. To the extent a response is required, Dey denies all allegations contained in Paragraphs 700 through 704 of the AMCC.

#### **COUNT VII (INDIRECT PURCHASER – TOGETHER RX)**

705. Answering Paragraph 705 of the AMCC, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 704 of the AMCC. The remaining allegations in Paragraph 705 are directed to another defendant and concern claims which are not asserted against Dey and, therefore, require no response from Dey. To the extent a response is required, Dey denies all of the remaining allegations contained in Paragraph 705 of the AMCC.

706-708. The allegations in Paragraphs 706 through 708 of the AMCC are directed to another defendant and concern claims which are not asserted against Dey. Therefore, these paragraphs of the AMCC require no response from Dey. To the extent a response is required, Dey denies all allegations contained in Paragraphs 706 through 708 of the AMCC.

#### **COUNT VIII (RICO – TOGETHER RX)**

- 709. Answering Paragraph 709 of the AMCC, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 708 of the AMCC.
- 710-725. The allegations in Paragraphs 710 through 725 of the AMCC are directed to another defendant and concern claims which are not asserted against Dey. Therefore, these paragraphs of the AMCC require no response from Dey. To the extent a response is required, Dey denies all allegations contained in Paragraphs 710 through 725 of the AMCC.

#### **COUNT IX (CIVIL CONSPIRACY – PBMs)**

- 726. Answering Paragraph 726 of the AMCC, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 725 of the AMCC.
- 727. Dey denies that Plaintiff CMHV is entitled to maintain this action in the manner alleged or that CMHV is a proper class representative. Dey denies having knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 727 of the AMCC and, therefore, denies those allegations.
- 728-731. To the extent the allegations in Paragraphs 728 through 731 of the AMCC and subparts refer to the knowledge, conduct or actions of persons, entities or defendants other than Dey, Dey denies having knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Dey denies the remaining allegations in Paragraphs 728 through 731 of the AMCC.
  - 732-733. Dev denies the allegations in Paragraphs 732 and 733 of the AMCC.

#### X. CIVIL CONSPIRACY (TOGETHER RX)

734. Answering Paragraph 734 of the AMCC, Dey realleges and incorporates its responses to the allegations in Paragraphs 1 through 733 of the AMCC.

735-741. The allegations in Paragraphs 735 through 741 of the AMCC are directed to another defendant and concern claims which are not asserted against Dey. Therefore, these paragraphs of the AMCC require no response from Dey. To the extent a response is required, Dey denies all allegations contained in Paragraphs 735 through 741 of the AMCC.

## UNNUMBERED "WHEREFORE" PARAGRAPH AND REQUEST FOR JURY TRIAL

Dey denies Plaintiffs are entitled to a judgment or any other relief requested in their Prayer for Relief and "WHEREFORE" paragraph following Paragraph 741 of the AMCC.

#### AFFIRMATIVE AND OTHER DEFENSES

# **First Defense**

Plaintiffs and the putative class fail to state a claim against Dey upon which relief may be granted.

## **Second Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the political question and separation of powers doctrines.

#### **Third Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the filed rate doctrine.

#### **Fourth Defense**

Plaintiffs and the putative class have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Dey as alleged in the AMCC.

# **Fifth Defense**

To the extent Plaintiffs and/or any member of the putative class obtain recovery in any other case predicated on the same factual allegations, that Plaintiff or purported class member is

barred from seeking recovery against Dey based on the AMCC pursuant to the doctrines of res *judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

## Sixth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the First

Amendment to the United States Constitution and the analogous provisions of the Constitutions
of the States of California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New

York, Pennsylvania, Texas, Washington and any other States whose laws are or become relevant
in the course of this multidistrict litigation.

## **Seventh Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Dey in judicial, legislative or administrative proceedings of any kind or at any level of government.

#### **Eighth Defense**

Plaintiffs and the putative class' claims are barred, in whole or in part, to the extent that Plaintiffs and the putative class members have released, settled, entered into an accord and satisfaction or otherwise compromised their claims.

#### Ninth Defense

Any and all actions taken by Dey with respect to any of the matters alleged in the AMCC were taken in good faith and in accordance with established industry practice.

#### **Tenth Defense**

Plaintiffs and the putative class' state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and

Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

# **Eleventh Defense**

Plaintiffs' and the putative class' claims are preempted by the dormant Commerce Clause of the United States Constitution.

#### **Twelfth Defense**

Plaintiffs' and the putative class' claims against Dey are barred because Dey has complied with all applicable regulations of the federal and state governments.

## **Thirteenth Defense**

Plaintiffs' and the putative class' claims against Dey are barred, in whole or in part, by the applicable statutes of limitations and repose.

## **Fourteenth Defense**

Plaintiffs' and the putative class' claims against Dey are barred, in whole or in part, by the doctrines of laches, estoppel, waiver, and unclean hands.

#### **Fifteenth Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, because they violate Dey's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as all applicable state constitutions, insofar as Plaintiffs and the putative class members seek to impose liability retroactively for conduct that was not actionable at the time it occurred.

#### **Sixteenth Defense**

Plaintiffs and the putative class fail to state with particularity facts to support the fraud and/or fraudulent concealment allegations against Dey contained in the AMCC.

#### **Seventeenth Defense**

Plaintiffs and the putative class failed to plead with particularity their multi-source medicine allegations against Dey in the AMCC.

## **Eighteenth Defense**

Plaintiffs' and the putative class' RICO claims against Dey are barred, in whole or in part, due to their failure to plead facts showing: (i) that Dey and the PBMs are ongoing organizations whose members function as continuing unit and share common purposes as required by *United States v. Turkette*, 452 U.S. 576, 583 (1981); (ii) the existence of a RICO enterprise as required by 18 U.S.C. § 1962(c); and (iii) that Dey conducted the affairs of the alleged enterprises as required by 18 U.S.C. § 1962(c).

#### **Nineteenth Defense**

Plaintiffs and the putative class fail to allege with particularity their civil conspiracy claims against Dey as required by Fed. R. Civ. P. 9(b), including but not limited to the failure to allege a concerted action or a coercive conspiracy.

#### **Twentieth Defense**

Plaintiffs' and the putative class' civil conspiracy claims against Dey are barred, in whole or in part, because they are duplicative and improper under Massachusetts law. *See Grant v. John Hancock Mut. Life Ins. Co.*, 183 F. Supp. 2d 344, 364 (D. Mass. 2002).

#### **Twenty-First Defense**

Dey denies that Plaintiffs and the putative class have valid consumer protection claims against Dey under California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington or any other State whose law is or becomes relevant in the course of this multidistrict litigation. However, if such claims are found to exist, Dey pleads all available defenses under the Acts.

# **Twenty-Second Defense**

Plaintiffs and the putative class lack standing to bring their asserted consumer protection claims against Dey under certain state consumer protection laws, including without limitation those of Delaware, Florida, Louisiana, New Jersey, Pennsylvania and Washington.

#### **Twenty-Third Defense**

Any allegedly fraudulent statement or conduct of Dey was not consumer-oriented as required under certain consumer protection law, including without limitation that of Minnesota and New York.

## **Twenty-Fourth Defense**

Plaintiffs' and the putative class' claims against Dey for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

# **Twenty-Fifth Defense**

Plaintiffs' and the putative class' claims for injunctive relief against Dey are barred by the doctrines of *in pari delicto* and/or unclean hands.

#### **Twenty-Sixth Defense**

This action cannot be maintained as a class action because the certification and maintenance of this action as a class would violate the separation of powers provisions of the United States Constitution and would be an unconstitutional usurpation of authority reserved to the legislative branch.

# **Twenty-Seventh Defense**

This action cannot be maintained as a class action because the claims of Plaintiffs and the putative class cannot be properly joined with one another because they did not arise out of the same transaction, occurrence, or series of transactions or occurrences.

## **Twenty-Eighth Defense**

This action cannot be maintained as a class action because the named Plaintiffs and the putative class cannot satisfy the procedural requirements of Fed. R. Civ. P. 23.

## **Twenty-Ninth Defense**

This action cannot be maintained as a class action because the questions of fact at issue are not common to the alleged class, but rather, are highly specific and will vary dramatically from person to person and entity to entity.

#### **Thirtieth Defense**

This action cannot be maintainable as a class action because class certification would violate Dey's rights provided by the Fifth, Seventh and Fourteenth Amendments to the United States Constitution as well as by the Constitutions of the States of California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington and any other States whose laws are or become relevant in the course of this multidistrict litigation, including but not limited to Dey's right to procedural and substantive safeguards, which include traditional defenses to liability.

#### **Thirty-First Defense**

Third party payor plaintiffs' and third party payor putative class members' claims against Dey are barred, in whole or part, with respect to any alleged overcharge or supracompetitive price on the ground that third party payors passed on any effect of the alleged supracompetitive prices to their customers or employees in the form of higher premiums.

#### **Thirty-Second Defense**

Plaintiffs' and the putative class' claims against Dey are barred, in whole or in part, with respect to any alleged overcharge or supracompetitive price because such supracompetitive price, if any, was absorbed, in whole or part, by a person and/or entity which purchased the medicine

directly, and/or by an intermediate indirect purchaser, and was not passed through to the Plaintiffs and putative class members.

## **Thirty-Third Defense**

Plaintiffs' and the putative class' claims against Dey are barred, in whole or in part, due to their failure to join indispensable parties.

## **Thirty-Fourth Defense**

Plaintiffs' and the putative class' claims against Dey are barred, in whole or in part, because they have suffered no damages as a result of the matters alleged in the AMCC.

## **Thirty-Fifth Defense**

Plaintiffs' and the putative class' claims are barred, in whole or in part, because any injuries sustained by Plaintiffs or the putative class were the result of intervening or superceding conduct of third parties.

#### **Thirty-Sixth Defense**

Plaintiffs' and the putative class' claims against Dey for damages are barred, in whole or in part, because they failed to mitigate their damages, and their failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Dey.

#### **Thirty-Seventh Defense**

Plaintiffs' and the putative class' claims against Dey for damages are barred, in whole or in part, because they would be unjustly enriched if allowed to recover any portion of the damages alleged in the AMCC.

## **Thirty-Eighth Defense**

Dey is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs and/or the putative class, with respect to the same alleged injuries.

#### **Thirty-Ninth Defense**

Plaintiffs' and the putative class' claims against Dey for damages are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that plaintiffs and/or putative class members have received and paid for medicines manufactured, marketed and sold by Dey after the filing of Plaintiffs' original Complaint.

## **Fortieth Defense**

Any damages recovered by the Plaintiffs and the putative class from Dey must be limited by the applicable statutory ceilings on recoverable damages.

#### **Forty-First Defense**

Plaintiffs and the putative class fail to allege facts or a cause of action against Dey sufficient to support a claim for attorneys' fees, treble damages and/or legal fees.

#### **Forty-Second Defense**

To the extent punitive damages are sought, Plaintiffs' and the putative class' punitive damages claims against Dey cannot be sustained because an award of punitive damages would violate the United States Constitution, Excessive Fines Clause of the Eighth Amendment, U.S. Const. amend. VIII and the Due Process Clauses of the Fifth and Fourteenth Amendments, U.S. Const. amend. V & XIV, § 1 and the analogous provisions contained in the Constitutions of the States of California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington and any other States whose laws are or become relevant in the course of this multidistrict litigation.

#### **Forty-Third Defense**

Dey adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

## **Forty-Fourth Defense**

Dey hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense. Dey also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part thereof, is governed by the substantive law of a state other than California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington and/or any other State law which is or becomes relevant in the course of this multidistrict litigation.

# **Forty-Fifth Defense**

To the extent equitable relief is sought, such claims cannot be sustained because Plaintiffs and the putative class have an adequate remedy at law.

## WHEREFORE, Dev respectfully requests that the Court:

- 1. Dismiss the Corrected Amended Master Consolidated Class Action Complaint Modified Per the Court's Instructions at the November 21, 2003 Hearing With Amgen Amendments with prejudice and enter judgment in favor of Dey and against Plaintiffs;
- 2. Award Dey its costs, expenses, and attorneys' fees; and
- 3. Grant Dey such other, further, and different relief as the Court deems to be just and proper.

**Dated:** July 29, 2004

Respectfully submitted,

**KELLEY DRYE & WARREN LLP** 

By: s/ Philip D. Robben [signature on file]
Paul F. Doyle

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Attorneys for Defendant Dey, Inc.

# **CERTIFICATE OF SERVICE**

I hereby certify that on this 29th day of July, 2004, a true and correct copy of the foregoing document was served upon all counsel of record by electronic service pursuant to CMO No. 2, by causing a copy to be sent to Verilaw Technologies for posting and notification.

 s/ Philip D. Robben [signature on file]
Philip D. Robben

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